Regulatory Reforms Team
Therapeutic Goods Administration
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Dear Madam/Sir

Accord is pleased to provide this submission to the TGA's Consultation: *Options for the future regulation of "low risk" products* (Consultation Paper*).*

Accord is the peak national industry association representing the manufacturers and marketers of formulated hygiene, cosmetic and specialty products, their raw material suppliers, and service providers. Accord member companies make and/or market fast-moving consumer and commercial goods including hygiene, cosmetics and specialty products, sunscreens, food contact sanitisers, industrial and agricultural sanitisers, disinfectants and specialty commercial products. Member companies include large global consumer product manufacturers as well as small dynamic Australian-owned businesses with 80 percent of members operating as SME (<200 employees). A list of Accord member companies is available on our website: http://accord.asn.au/about/members/.

Headline statistics[1] for our industry's economic footprint include:

- Estimated annual retail-level sales of industry products nudging the $10 billion mark.
- Accord's membership is approximately 100 companies.
- Collectively, Accord member companies directly contribute more than 15,000 full-time equivalent jobs.
- Nationally, more than 180 offices and more than 60 manufacturing sites are operated by Accord member companies.

Accord congratulates the TGA in its approach to defining "low risk" to achieve implementation of reform measures arising from the recommendations by the Expert Panel Review. The concept of regulatory familiarity for certain products is of importance and its application in this context will assist in delivering tangible reforms. As indicated in the tables on pages 12-14 the products under consideration for reform are generally accepted as being of low risk.

The continued push for reform by industry to these low risk products is based on the principles of good regulation in achieving a regulatory environment which is the minimum but effective level required to achieve the desired outcome within a risk management framework. An effective framework not only delivers benefits to industry, but also enables regulatory agencies to focus their efforts where a higher level of risk exists. This is a more efficient and effective use of regulatory resources.

[1] Results from Accord Industry Size and Scale Survey 2016

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The current hierarchy of low risk products (Figure 1 of the consultation paper) includes sunscreens which are divided into primary or secondary sunscreens, of which secondary sunscreens are noted as being regulated as cosmetics. It is important to note that the TGA currently regulates both primary and secondary sunscreens, with secondary therapeutic sunscreens being those products generally recognised by consumers as cosmetics (due to their primary effects e.g. moisturising) but which have an SPF >15 taking them into the TGA's jurisdiction.

In the Consultation Paper, examples of products with a degree of regulatory familiarity, i.e. those that are used every day by consumers and have well known risks include tampons and hard surface disinfectants. Included in this list should also be sunscreens, hospital grade domestic disinfectants and personal lubricants.

Accord has long supported the Government's "Accepting Trusted International Standards" policy announced in 2014. The policy states that:

> *If a system, service or product has been approved under a trusted international standard or risk assessment, then our regulators should not impose any additional requirements for approval in Australia, unless it can be demonstrated that there is a good reason to do so.*

It seems that to date, the intent of this policy has been lost in discussions on the differences between overseas regulatory systems and barriers to the acceptance of international assessments and standards. We look forward to further consideration by the TGA of the opportunities this policy could provide if fully embraced.

Accord is heartened by the methodology adopted by the TGA to demonstrate "low risk" and we hold expectations that on this basis, meaningful reform will be achieved. We look forward to continuing to work with the TGA and other stakeholders to deliver reform to the products under consideration in the Consultation Paper.

[redacted]

Yours sincerely

[approved for electronic submission]

Bronwyn Capanna
Executive Director

12 May 2017

Nappy Rash cream - Options for reform

Option 1 – Maintain the status quo regulation of nappy rash and skin care products – not supported

Option 2 – Review of medical device nappy rash products – supported
It is recognised in the Consultation Paper that there can be misclassification of these products under the current system. This option is consistent with other recommendations for Medical Devices Class 1 as proposed. Accord members note that the guidance information to sponsors on Medical Devices Class 1 could be strengthened to provide further clarity and to help avoid issues relating to misclassification.

Option 3 – Exemption from listing in the ARTG - supported
While this option is supported for topical creams providing moisturising/barrier effects, we still have reservations regarding the requirement for these products to meet GMP and advertising pre-clearance. We note that the requirements for advertising therapeutic goods is also currently subject to reform proposals. It is our understanding that exempted TGA goods do not require GMP therefore it is unclear what the benefit would be for nappy rash creams to be exempt from listing but still be required to meet the regulatory requirements for a listed product. Rather than require GMP licencing the TGA could consider compliance with a monograph as an alternative.

Option 4 – Review of registered nappy rash active ingredients – supported

Option 5 – Exclude nappy rash products from the regulatory framework – not supported

Antiperspirants - Options for reform

Option 1 – Maintain the status quo regulation of antiperspirant preparations – see comments for Option 2

Option 2 – Exclude antiperspirants from the regulatory framework - supported

It is Accord's understanding that this is already the practice for antiperspirants that derive their properties from inorganic salts of aluminium, zinc or zirconium because of reforms to products at the therapeutic/cosmetic interface. As indicated in the Explanatory Memorandum for amendments to the Industrial Chemicals (Notification and Assessment) Bill for cosmetics in 2007:

> *In November 2005, the proposed reform of cosmetic regulation in Australia was endorsed (as reflected in the Regulation of Cosmetic Chemicals: Final Report and Recommendations) including the establishment of NICNAS Cosmetic Guidelines. In relation to cosmetics, the major objectives of the agreed reforms were to:*
>
> - *clarify the interface between TGA and NICNAS in terms of the regulation of cosmetics;*
> - *enable a greater range of cosmetics to be regulated by NICNAS rather than the TGA;*
> - *improve regulation at the interface for identified product types, including changes that could enhance the transparency and useability of existing regulatory documents; and*
> - *specifically address issues dealing with **antiperspirants**, mass-market antidandruff, shampoos, moisturisers with SPF, antibacterial skin washes, and anti-acne cleansers.*[2]

The NICNAS Cosmetic Guidelines[3] under product categories for personal hygiene, include reference to deodorants and antiperspirants as examples of product types. However, when the Therapeutic Goods (Excluded Goods) Order No. 1 of 2011 was amended to reflect the cosmetic reforms of 2007, antiperspirants were omitted. The TGA should amend this anomaly and expand the scope of the entry in the excluded goods order to exclude all topical antiperspirants from the TGA's regulatory framework.

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[2] Industrial Chemicals (Notification and Assessment) Amendment (Cosmetics) Bill 2007, Explanatory Memorandum

[3] NICNAS Cosmetic Guidelines 2007 as amended 2011

Other low risk registered non-prescription (OTC) medicines - Options for reform

The product types which represent Accord's membership are as follows:

- Registered desensitising toothpastes
- Menthol-based inhalers and chest rubs
- Antiseptic mouth washes
- Acne treatments containing benzoyl peroxide
- Rubefacient preparations for minor aches and pains of muscles (e.g. methyl salicylate, menthol, capsicum and other traditional use complementary medicine ingredients) but not creams or ointments containing a non-steroidal anti-inflammatory medicine
- Antidandruff and antifungal shampoos

Option 1 – Maintain the status quo regulation of low risk OTC medicines – not supported

Option 2 – Review of eligibility of active ingredients to become Listable - supported

In addition to the product categories listed in the Consultation Paper, the following should also be included as part of the review of low risk registered products:

- medicated soaps,
- antibacterial skin washes,
- anti-acne skin cleaners and
- antiseptic hand wipes.

While the reforms of 2007 did move some borderline products into the cosmetic category, controls were applied which deemed them to be cosmetic. The current review process provides an opportunity to consider whether the remaining products initially considered in the Newgreen[4] reform process could now have a lighter regulatory touch through listing rather than registration on the ARTG.

[4] David B Newgreen, *Review of the regulation of products at the interface between cosmetics and therapeutic goods* March 2005

Hard surface disinfectants - Options for reform

Option 1 – Maintain the status quo regulation of hard surface disinfectants – not supported

Option 2 – Streamline the regulatory framework for hard surface disinfectants - supported

Streamlining and simplification of the regulatory framework by moving currently "registered" products to "listed" and "listed" to exempt is supported.

To deliver this simplification in practice, the regulatory treatment for products that would become "listed" or "registered" should remain in line with the current requirements particularly in relation to the information required to be submitted for pre-market review i.e. currently for "listed" products, microbial efficacy, stability and quality control data is not required. The new "listed" products could be self-assessed against performance criteria in a revised TGO 54 to maintain integrity and confidence in the system and in the quality of the products.

Current procurement requirements often require the AUST L or R number of a product for it to be considered for purchase. Moving forward, as more products may no longer carry an AUST L or R number, the engagement with States and Territories flagged in the consultation paper to address these issues will be of high importance.

Option 3 – Develop a series of monographs – supported in part

From the experience of our member companies, monographs tend to be highly prescriptive, based on current known chemistries and technologies, and therefore do not facilitate innovation. There may be categories of products within the scope of hard surface disinfectants that are suited to a monograph approach, and this could be explored further.

A monograph approach would need to be part of wider reforms i.e. in conjunction with Options 2 and 4, such that risk-proportionate pathways exist for the introduction of new innovative products.

A revised TGO 54 in line with current commercial practice would be a preferred alternative to new monographs, with the addition of information such as clarified definitions including "hospital grade"; examples of acceptable international test methods and performance requirements to demonstrate efficacy for specific claims for "listed" products.

Option 4 – Approval process for new ingredients - supported

Accord has long supported the Government's "Accepted Trusted International Standards" policy. Implementation of this option will remove duplicative regulatory requirements, and help to facilitate Australian consumers' access to the latest innovative products.

Option 5 – Declare hard surface disinfectants not to be therapeutic goods – not supported

Other matters

Use of the description "hospital grade"

The term hospital grade is well understood within the retail sector as a descriptor of efficacy and quality for both consumer and commercial disinfection products. The terminology has an

extremely high level of market penetration and is well understood by the consumer as an indicator of an efficacious and quality product. We see no reason to change current commercial practice and labelling. A clarified definition should be provided, linking the term to the efficacy of the product, rather than the situations in which the products may be used.

Regulation of hard surface disinfectants by other regulatory agencies

The APVMA also regulates hard surface disinfectants which can cause confusion in the market place as to which regulator is responsible for general purpose disinfectants. Consideration should be given to the current regulatory arrangements for all general purpose hard surface disinfectants with a view to aligning their regulatory treatment, preferably under the remit of a single regulator (i.e. the TGA).

Sunscreens - Options for reform

Sunscreens are important for the general wellbeing of Australian consumers and have been an essential part in the overall preventative strategy for skin cancer. Australia and New Zealand have the highest rates of skin cancer in the world. Key data[5] on the industry shows that global skincare brands such as Accord members: L'Oréal, Unilever, Procter & Gamble and Beiersdorf dominate the retail market. For 2016-17 industry revenue is expected to be worth $290M with strong annualised growth of 6.7% over the last five years. Australian industry over the last five years has made some headway, with export earnings and a growing array of innovative sun-care and skincare products underpinning this growth.

The introduction of regulatory changes in 2013 which allowed products with SPF50+ for sale in Australia, six years later than in comparable economies, has stimulated sales. The growth in sales from regulatory reforms which enable innovation in sunscreen product ranges demonstrates the potential benefits to consumers and industry from further reform in this area.

Accord members have a real interest in sunscreen reform, and as market leaders in both the primary and secondary sunscreen markets our sector has been recommending reform for a considerable period of time. Sales data[6] for sunscreens in mass market retail channels (including pharmacy and grocery but not including department stores) indicates:

Product category	**Market share of Accord members**	
	by value (AUD)	by volume (units)
All secondary sunscreens	88%	89%
Secondary sunscreens SPF30> (therapeutic)	77%	85%
Secondary sunscreens SPF15> (cosmetic)	90%	90%
Primary sunscreens (therapeutic)*	49%	45%

**Of the remaining market share approximately only 8-10% are represented by an alternative industry association*

Option 1 - Maintain the status quo regulation of sunscreens – not supported

Option 2 – Streamline the regulatory pathways for sunscreen regulation – supported

Reform of sunscreens is urgently needed to gain greater regulatory efficiency, reduce the regulatory burden on industry, increase global harmonisation and encourage product innovation and availability to Australian consumers. For industry, the aim is to drive down costs of production, increase competition and enable Australian consumers to have faster access to better performing sunscreens as technology develops.

Innovative products with better application properties will encourage consumers to use these products liberally and frequently as intended. If products are more accessible and affordable, cost should not be an inhibiting factor in the proper application and reapplication of sunscreen products.

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[5] IBISWorld Industry Report OD5413 *Sunscreen and Other Skincare Product Manufacturing in Australia*, August 2016

[6] Based on aggregated sales data provided by Accord members (2016)

Accord, on behalf of a responsible industry, recently launched a new public education website: Sunsible™ with advice to the community on how to better use sunscreens to stay safe in the sun during summer and how to use sunscreens sensibly to get the best possible level of protection (www.sunsible.org.au).

We support the proposal to streamline the regulatory pathways for sunscreen regulation. In particular, we are supportive of the proposal to exclude all secondary sunscreens as defined in AS/NZS 2604:2012 as well as primary sunscreens with SPF claims of 4 or less from the TGA regulatory framework.

AS/NZS 2604:2012 defines secondary sunscreens as follows:

> 4.10 Secondary Sunscreen Products
>
> A product that is represented as having a primary function other than sun protection whilst providing some protection of the skin from ultraviolet radiation.
>
> 4.10.1 *Skin care*
>
> (a) Moisturising products for face, hand and body that are secondary sunscreen products for dermal application, including anti-wrinkle, anti-ageing and skin whitening products.
>
> (b) Sunbathing products that are secondary sunscreen products (e.g. oils, creams or gels), including products for tanning without sun, and 'after sun' skin care products.
>
> 4.10.2 *Colour cosmetic and lip products*
>
> Colour cosmetics products that are secondary sunscreen products and are either tinted bases or foundations (make-up), or products intended for application to the lips (tinted or untinted) (pp9).

AS/NZS 2604:2012 provides enhanced consumer protection for both primary and secondary sunscreens regardless of the regulator, i.e. TGA, NICNAS or ACCC. The testing requirements for both classes of sunscreen products are now aligned. Given this advance, we do not see that there is any consumer detriment by implementing this reform. The requirement of AS/NZS2604:2012 for both primary and secondary sunscreens ensures that all Australians have access to high quality sun protection.

While we support the simplified approach to the regulation of primary sunscreens, further comments regarding the regulation of primary sunscreens are discussed under Option 7. The only concern which has been raised is in regard to allowable high level claims which under the current situation puts primary sunscreens into the registrable category. Given the innovation occurring in sunscreen technology we would want primary sunscreens to continue to be able to make high level claims as listable products.

We are unclear as to why the removal of the Cosmetic Standard should impact on the claims which secondary sunscreens are able to make. The Cosmetic Standard was meant to reflect the Excluded Goods order and for the most part it does. Accord has always maintained that the Cosmetic Standard is a duplication of existing regulatory requirements and is therefore unnecessary. We maintain this view and do not consider that claims on secondary sunscreens products, which are essentially cosmetics, would present any regulatory challenges. Nor do we support the contention in the Consultation Paper that consumers are confused between primary and secondary sunscreen products. There is no evidence provided to substantiate this claim.

The demarcation between primary and secondary sunscreen products as they are presented to consumers is clearly defined by several factors including:

- Pack size
- Location in store
- Product presentation (including claims and directions for use)
- Price.

An additional benefit to industry from removing the Cosmetic Standard would be the alignment of transition times from compliance with the 1998 sunscreen standard to the 2012 standard. The TGA has allowed a seamless transition enabling industry to make the decision when to phase out the 1998 standard while NICNAS has mandated that all products imported after 1 August 2018 must comply with the 2012 standard. The TGA's approach recognising that market forces will determine the most appropriate approach should be adopted for all secondary sunscreens rather than imposing an arbitrary date.

Option 3 – Prevent all secondary sunscreens from making SPF claims – not supported

Option 4 – Creation of a GMP standard for primary sunscreens – supported in part

Cost of doing business in Australia
The World Bank Group places Australia at 15 out of 190 economies in its Ease of Doing Business Index[7]. The Index is a benchmark study of regulatory burden. While this may seem reasonable, New Zealand, our closet trading partner is ranked at Number 1. Australia which was ranked 6 in 2006 has steadily lost its competitiveness and was ranked 10 in 2015; 13 in 2016 and is currently ranked 15 for 2017. An area where Australia is doing poorly is trading across borders where we are ranked 91. The government's policy of Accepting Trusted International Standards, was in part, an effort to address this problem by reducing duplication of regulatory approvals, reduce delays, increase competition and improve business competitiveness in Australia. This supports the government's overall objective to reduce the regulatory burden on business, community organisations, families and individuals. One way of reducing regulatory burden is to remove unnecessary duplication of multiple regulatory processes. This includes recognition of overseas approvals processes and avoiding extra delays that result from imposing Australian-specific requirements when an approved system, service or product already exists in an international market.

The cost to industry of importing the same products as are sold overseas but being required to meet specific Australian requirements can be quite high. Members have indicated that the cost for sunscreens meeting PICs GMP requirements compared to the costs of supply for the same product as a cosmetic in the EU is around $200K plus (Attachment 1).

We are pleased to note that the Consultation Paper recognises the regulatory approaches by USA, Canada and the EU as comparable to requirements for listed medicines in Australia. This supports the TGA utilising through the government's Accepting Trusted International Standards policy, a process of accepting these products as suitable for the Australian marketplace without further regulatory intervention. If the approaches are aligned as stated in the Consultation Paper then we see no reason why imported products from these advanced

[7] http://www.doingbusiness.org/rankings

economies should be subject to additional regulation for the Australian market, particularly additional GMP requirements, or additional test data for active or excipient ingredients.

Where an international standard or risk assessment already exists, the Government has decided that this should be adopted unless it can be demonstrated that there is a good reason to maintain a unique Australian standard or risk assessment. The policy seeks to adopt an approval process or certification for a service, process or product that already exists in an international market that can be trusted by the Australian Government and the community.

Sunscreen GMP

Accord members support flexibility for GMP which is suggested in the Consultation Paper. Two options are provided: continued acceptance of PICs and adoption of alternative pathways or processes suitable for sunscreens. The cost of meeting an oral medicines GMP standard for a topical non-sterile cream continues to be of concern to Accord.

Accord has always supported the requirement for primary sunscreen manufacturers to comply with an independently audited GMP standard. This process however, should be internationally aligned rather than uniquely Australian. Unique requirements would create similar problems and costs associated with the current PICs GMP process. An Accord member company advises that:

> *We have a vast range of sunscreen products globally. Unfortunately, the current regulatory environment denies us the ability to introduce these to Australian consumers. Whilst their efficacy is verified to global standards (ISO 24444 for example), introduction is impossible due to the need to comply with specific OTC-grade ingredients, use of UV filters which are not approved in Australia but approved in Europe, or need to produce in a medicinal-GMP approved facility. The irony of course, given the times, is that consumers can just as easily purchase the same range from our global stable through the variety of online suppliers presently in market.*

Several options exist to facilitate recognition of regulatory equivalence of GMP for sunscreens. The EU Regulations require GMP for cosmetic products and recognise ISO 22716 Cosmetic GMP. The TGA could accept ISO 22716 Cosmetic GMP as the basis for an acceptable level of GMP for sunscreen products.

Industry would also prefer, non TGA assessors allowed to inspect low risk therapeutic sunscreens in overseas manufacturing facilities. A precedent for this under PICs has already been established by Health Canada which allows qualified external inspectors to carryout inspections against PICs for overseas sunscreen manufacturers and issue GMP clearances as they do when their own inspectors inspect. The current TGA approved list of notified bodies could be a suitable source for inspectors. Many of these already do inspections against PICs requirements and also ISO 22716 requirements.

Qualified inspectors from notified bodies are in countries where there are manufacturing plants, they speak the local language, are not reliant on filtered translations and can schedule an inspection within a few weeks at a cost of around $10,000. This is a more timely, reliable and cost effective alternative than the use of TGA inspectors which are required to fly in from Australia at a cost of around $45-60,000 and for which there may be a delay of up to two years before an inspection can be made.

Alternatively, the TGA could streamline PICs GMP requirements to be more appropriate for non-sterile topical applications such as sunscreens. Rather than creating a new Sunscreen GMP it may be preferable to exclude certain elements of PICs for sunscreen manufacturing

such as the facility air sterile filtration systems as identified in Option 4. Again, the streamlined PICs GMP could also be inspected by notified bodies as an inspection process for sunscreens only. An alternative approach could be that the TGA conduct desk audits of overseas manufacturing sites for sunscreens rather than inspections.

Since the Consultation Paper advises that the TGA's regulatory approach is aligned with the US and Canada then the TGA should automatically accept GMP clearance licenses from the US FDA and Health Canada including their time frames i.e. US FDA license approvals are generally 5 years. This should be adopted as a matter of principle under the government's Accepting Trusted International Standards policy for comparable regulators. Attachment 2 provides case studies of global leaders in sunscreen manufacturing supplying product around the world yet unable to meet TGA inspection requirements despite meeting their local regulatory requirements.

Option 5 – New ingredient approval process – supported

Accord supports the acceptance of new approval processes for ingredients based on the Accepting Trusted International Standards Policy. This would broaden the availability of ingredients already in commercial use in comparable countries for use in Australia. We would encourage a greater use of acceptable sources of approved lists beyond just comparable regulators recognising that industry based processes can have the same rigour as regulators and are acceptable alternatives by regulators in comparable economies. For example, International Fragrance Association (IFRA) Standards have been adopted in law by the New Zealand Environmental Protection Authority (EPA) under the Cosmetic Products Group Standard 2006 and are acceptable to the European SCCS.

The IFRA Code of Practice applies to the manufacture and handling of all fragrance materials for all types of applications and contains the full set of IFRA Standards. Abiding by the IFRA Code of Practice is a prerequisite for all fragrance supplier companies that are members of IFRA (either directly or through national associations). Industry is committed to compliance with the international risk management measures in the IFRA standards for fragrance materials as set out in their Code of Practice.

Many scheduling decisions made by the Advisory Committee on Chemicals Scheduling (ACCS) are consistent with the IFRA Standards. On the basis of existing practice, the TGA could adopt the IFRA Standards into the Poisons Standard and the 26BB "Permitted Ingredients" determination which would improve alignment with established overseas regulatory systems with no detriment to public health and safety.

Members advise that prior to the introduction of the permissible ingredients list for listed medicines, the TGA did not evaluate fragrances below 1%, as it does for excipients and no evaluation fee was imposed to have a fragrance approved. The formulation of a fragrance was supplied to the TGA via a Proprietary Ingredient (PI) application and the fragrance was reviewed by the TGA and issued with a Proprietary Ingredient (PI) number. Safety data was not usually required. The percentage of a fragrance in a sunscreen would be less than 1% of its formulation and typically for a leave-on product is around 0.1- 0.53%. The introduction of the 26BB "Permitted Ingredients" determination for listed products has created problems in the use of PIs. While the TGA claims there has been no regulatory change, members have consistently identified issues.

> *Example 1 – "Say it has a name change but the 100% formula remains the same. TGA refuse to change the name of the PI and insists submit a new one. But doing that*

disconnects the newly named PI from the ARTG entry user and triggers a need for a new application. Whereas retaining the PI number, despite the PI name change, recognises there is no formulation change it is not a separate and distinct good, and no basis for a new product entry."

Example 2 – *Confusion over assessment requirements for fragrance ingredients – advice from the TGA regarding changes arising from introduction of 26BB:*
"The Therapeutic Goods Act 1989 states that when listing a product under s26A, the applicant must certify under s26A(2)(ca) that the medicine does not contain an ingredient that is not specified in a determination under paragraph 26BG(1)(a). Therefore under the legislation, a listed medicine can only contain ingredients permitted for use in the Therapeutic Goods (Permissible Ingredients) Determination, flavours and fragrances are not exempt from this requirement. ***It appears this may have been an inconsistency carried over in the guidance from before the introduction of the Permissible Ingredients Determination on 1 January 2016 (see FAQs for more information****). Thank you for bringing the inconsistency in the ARGCM to our attention, we will update this part of the guidance as soon as possible.*

Example 3 – *"Company X is having trouble in obtaining a PI approval – which has stopped the launch of a sunscreen worth $1M to its local business."*

To put the fragrance issue in context from an industry perspective, typically a fragrance for a sunscreen could be made up of 160 ingredients. The recent example that triggered the above response from the TGA in Example 2, indicated that 10 ingredients in a sunscreen fragrance were not on the ARTG and two were approved as flavours but not for fragrances. The TGA required all 12 ingredients to go through their toxicology section and have the ingredients' safety evaluated. A safety data submission to the TGA for 12 ingredients is approximately 12x100 pages per ingredient and the TGA cost to evaluate 1200 pages of data is $35,300. There is a chance that one of the fragrance ingredients may be found unacceptable and hence the whole fragrance fails and the $35,300 is essentially lost. The previous approach by the TGA allowed the flexibility to screen the ingredients in a formulation for a sunscreen fragrance used at up to 1% without evaluation. This approach appeared to be working well and industry is not aware of any problems which required a change to existing practices.

The TGA should act to remedy this situation to the practice which was in place prior to the introduction of the 26BB "Permitted Ingredients" determination. The acceptance of IFRA Standards as mentioned above would assist in this process.

The TGA approval system for active ingredients (UV Filters) for sunscreens duplicates the EC Regulations for Cosmetics requirements for UV Filters. In New Zealand, the EPA recognises new UV Filters as added to the EC Regulation for Cosmetics. NICNAS also has a separate approval system based on the TGA and EC Regulations but with additional local requirements.

If a company wants to use a UV Filter in primary and secondary sunscreens with SPFs up to SPF 30 or in cosmetic make-up products of any SPF then the UV Filter has to be approved by both TGA and NICNAS through separate applications. The TGA cost based on page count of 251-500 pages is $17,800 but more likely 501-1000 pages at a cost of $23,500. NICNAS cost for a Limited Notification with exempt information and variation of schedule data requirements is $17,300 reduced to $14,600 if already evaluated by TGA. Total cost $38,100 for unnecessary evaluation in Australia by two separate regulators using the same data and essentially the same criteria as the SCCS in Europe and a delay of at least 6 to 12 months while the Australian regulators complete their evaluations.

The US FDA does not require safety data for excipients to be submitted for evaluation prior to product supply. Ingredients are required to be Generally Recognised as Safe (GRAS) and

compliant with the FDA OTC Sunscreen Monograph. The FDA allows excipients to be named according to the International Cosmetic Ingredient Dictionary and Handbook (ICID) nomenclature system.

Health Canada has a naming system for excipients that uses where appropriate the TGA's AAN nomenclature, otherwise other names including ICID names can be proposed. The excipients need to be proposed and approved by Health Canada, but there appears to be no safety evaluation fees in having an excipient approved. There may be a reciprocal arrangement possible with excipients on the Health Canada data base not requiring evaluation again by the TGA. This arrangement should be explored with the TGA.

Accord has put together a table of international benchmarking of regulatory controls and costs for sunscreens at Attachment 3. The table demonstrates the additional costs incurred to market sunscreen products in Australia.

Option 6 – Alternative ingredient standards for excipients – supported

The requirement for pharmacopeia standards for ingredients of sunscreen products has been problematic for the cosmetic industry. Many of the excipients in sunscreens are also used in cosmetics and the requested animal toxicity data is often difficult to obtain. Due to the EU ban on animal testing which came into effect on 11 March 2013 obtaining animal test data has become more difficult and there are only a limited number of validated test alternatives.

In the past, the TGA has taken the position that excipients have a major impact on the quality of the product and that they can contribute to issues with the stability as well as the performance of sunscreen products. Industry has long disagreed with this position, and no evidence has been provided that such unique TGA testing of excipients improves the quality and safety of products available in the Australian market compared to those available in comparable jurisdictions. Sunscreen formulations are already subject to Australian specific stability requirements, so the requirement for stability and testing of excipient ingredients, in addition to that required for the product appear to be duplicative requirements and are not supported. These requirements are unique to Australia and result in a trade barrier.

Streamlining TGA Approval and Naming of Excipient Ingredients for Sunscreens
The current system of requiring all excipient ingredients to be named and approved by the TGA before a sunscreen can be listed on the ARTG is the other major cost and time consuming issue for sponsors of TGA therapeutic sunscreens after GMP inspections. Often there are duplicative assessments by both TGA and NICNAS of the safety of the same ingredient, one for therapeutic sunscreen use and the other for cosmetic sunscreen or other cosmetic use.

Unlike NICNAS, the TGA requires evaluation of all excipients irrespective of the percentage used. NICNAS allows self-assessment against specific criteria and annual reporting of ingredients that are non-hazardous and are used at 1% or less in unlimited volumes per annum and for ingredients in formulations at more than 1% which pose no unreasonable risk and are introduced at 10kg per annum or less. Ingredients of no unreasonable risk and introduced at up to 100kg per annum are eligible for notifications. Some ingredients such as colorants, UV filters, preservatives, bio accumulative and persistent environmental ingredients as well as prohibited cosmetic ingredients in the EU (Annex II) and US FDA banned ingredients cannot be self-assessed. The TGA could also consider such an arrangement for excipients for therapeutic sunscreens.

The difficulty in meeting the TGA's regulatory requirements for excipients can be summed up by this Accord member comment:

> *We have put one (1) product only through the TGA listing process since 2010 – there have been twenty odd (20) products that could have been listed but for the tox studies and approval process for the excipients, (we have probable 5-10 new excipients in our moisturisers each iteration / improvement), so these products are not sold at all in Australia.*
>
> *So it is not something we are trying to do at all anymore, the technology the rest of the world is using for these products is moving well ahead of the limited pallet of approved ingredients available in Australia and to add something new here is beyond impossible.*

Option 7 – Exclude all sunscreens from the regulatory framework – supported in-principle

Accord recognises that public concern over possible diminished quality standards will play a significant part in challenging reform. The TGA will continue to be pressured by various stakeholders to implement strategies to reduce melanoma rates and any reform to sunscreens will likely be seen by these stakeholders as a threat to existing standards. Interestingly New Zealand has a much lighter touch for the regulation of sunscreens while Australia has adopted a rigid high level of regulatory intervention for these products yet the skin cancer rates in New Zealand and Australia are approximately the same.

This option would regulate sunscreens as cosmetic products as they are in Europe and those economies which have adopted the European Commission Regulation 1223 (2009) on Cosmetic Products.[8] Examples of economies outside of Europe which have adopted the EU requirements are New Zealand, South Africa, Russia, Brazil, Turkey and the ASEAN Economic Zone. The EU Cosmetic Regulation provides for very comprehensive requirements on product safety, stability, contamination, positive and negative lists of ingredients, consumer labelling and GMP for manufacturing.

Australia does not have a comparable scheme to the EU with regard to cosmetic regulation. This function is spilt between NICNAS for ingredient assessment; the ACCC for consumer protection, misleading and deceptive conduct, ingredient labelling, product safety and product liability; and the chemical scheduling process for the control of individual ingredients as required.

An alternative option to excluding all sunscreens from the TGA's regulatory framework but still maintaining a lighter regulatory touch which is appropriate for these low risk products is to exempt sunscreens from ARTG listing and develop a Therapeutic Goods Order or a sunscreen monograph to maintain controls.

A sunscreen Therapeutic Goods Order (TGO) could be developed to maintain controls and offer an alternative to the ARTG listing and to PIC/s GMP licencing. The use of a TGO approach has a regulatory parallel with the US FDA. The TGO could incorporate the requirements of the Australian/New Zealand Sunscreen Standards (AS/NZS 2604:2012 and

[8] Commission of the European Communities, 22 December 2009, Regulation (EC) No 1223/2009 of the European Parliament and of the Council of 30 November 2009 on Cosmetic Products, in *Official Journal of the European Union*, L342/59.

AS/NZS 2604:1998) and elements of the Australian Regulatory Guidelines for Sunscreens (ARGS) (November 2012).

Additional requirements to address safety, quality and efficacy include:

- a list of approved active ingredients;
- efficacy requirements as contained in AS/NZS 2604:2012 or equivalent internationally accepted standards;
- stability requirements to internationally accepted standards; and
- a system of GMP appropriate for sunscreens independently verified by a third party.

The recent introduction of new labelling requirements for medicines through TGO 91 and 92 has increased confusion as to labelling requirements for sunscreens. A labelling order for oral medicines creates difficulties for topical applications particularly those which are generally recognised as fast moving consumer goods and which already have a high degree of consumer familiarity. The new labelling requirements will not assist with consumer comprehension for primary sunscreens and may in fact result in less comprehensible labels. This is another example of the inappropriateness of controlling topical products as if they were oral medicines.

Tampons and Menstrual Cups - Options for reform

Accord member companies do not manufacture menstrual cups. Our comments are limited to tampons only.

Option 1 – Maintain the status quo regulation of tampons and menstrual cups

Following Option 2, there is minority member support for this Option as a second preference. Ensuring continued adherence to the Australian Standard and maintenance of consumer confidence in these products were the main drivers for preferring this Option over Option 3.

Option 2 – Exemption from listing in the ARTG - supported

Accord member companies support Option 2 as the preferred option and have expressed a preference for maintaining tampons within the TGA regulatory environment. As detailed under Option 1, adherence to the Australian Standard and maintenance of consumer confidence were the main drivers for preferring this Option.

Under the Accepting Trusted International Standards Policy, members support the acceptance of products from comparable economies without further testing such as those meeting the EU Edana test method, US FDA or Health Canada requirements.

Option 3 – Exclude tampons and menstrual cups from the regulatory framework

Following Option 2, there is minority member support for this Option as a second preference. If this Option were to be pursued, there would need to be a mechanism by which the Australian Standard would be mandated (possibly as a mandatory product standard under the ACCC) in order to maintain confidence in the quality and safety of the products.

Other matters

<u>Review of AS 2869-2008 Tampons – Menstrual</u>
Accord members recommend that AS 2869-2008 Tampons – Menstrual be reviewed given that the Standard is almost 10 years old. There are opportunities to align the Australian Standard with international practices as there have been innovations which can be applied to Australia.

Low risk products that are currently considered medical devices

Action 1 - Systematically review the ARTG for potential non-therapeutic goods - Supported.

Action 2 - Engage with the States and Territories - Supported.

This action is supported but Accord recommends that discussion be broadened to include other products which may be affected as a result of the reform process such as disinfectants which are also subject to hospital procurement processes.

Action 3 - Update the Excluded Goods Order - Supported.

Action 4 - Review Class 1 medical device ARTG entry process - Supported.

Accord recommends that consideration be given to providing greater guidance for lower class medical devices to assist with allowable claims and ARTG entries overall. This could be part of the TGA's current strategy on improving access to information for SMEs.

Accord recommends that the TGA should align Medical Devices Class 1 with EU classifications rather than make changes to certain product categories based on unique Australian requirements, for example: imported sticking plasters from the EU with animal origin should remain under the current classification of Medical Devices Class 1 and not be reclassified to Class 3 devices.

It is also recommended that personal lubricants were another device which could also be included for review. Lubricants for personal use could be classified as exempt or excluded. The scope of these products would need to be clearly defined.

ATTACHMENT 1

Schedule of costs for sunscreens meeting TGA requirements compared to the cost of supply for same products as cosmetics

Accord members have captured some of the costs associated with registering existing cosmetic sunscreen products as therapeutic products with the TGA. A schedule of costs which are additional requirements to that of getting products onto the market as cosmetics has been developed below. This current version is based on 2017 costs.

Cost Item	**Cost $ value**
Sourcing raw materials that meet OTC-monograph specifications for: actives; excipients, water	Estimated $13k per ingredient 51-250 pages
TGA GMP overseas inspections	$45k - $60k
Warehouse inspections	$30k - $55k
Undertaking Product Quality Reviews (PQRs)	$10k - $15k per formulation
Undertaking stability trials for at least two production scale batches annually	$15k minimum per formulation per packaging per batch ($270k in sunk costs has been reported)
Registering new actives	$50k minimum
Registering new excipients	$13k - $20kmin
Local re-testing if water resistance is claimed	$7.5k - $20kper formulation
Labelling changes to meet TGA requirements	$5k - $10k depending on volume of print run
BP Preservative efficacy testing/stability	$2K per product
Opportunity Costs	Unquantifiable

ATTACHMENT 2

International benchmarking of regulatory controls and costs for sunscreens

Country	Regulatory Classification	Excipient approval	Active approval	Formulation approval	Pre-market registration	GMP	Packaging & Labelling	Pre-market advertising approval
Australia	Therapeutic	$10K-$20K for new excipient and for any new ingredients in a Proprietary Ingredient for a fragrance (previously free). Expect multiple ingredients in fragrances to be new i.e. not on the ARTG	Yes - can cost $20K for new active	Yes – can cost $7.5K - $10K per formulation	Yes - $760 annual fee for each listed medicine	PIC/S GMP (average cost $45k to $60K) Cost of inspecting warehouses $20K - $50K	Yes - Medicines labelling, Approval number on packs Can cost $5 - $10K per print run	Yes - All TV/print approved by ASMI advertising, Free to air
	Cosmetic	Yes – all ingredients required to be on AICS or meet exemption requirements – can cost $15K- $20K for new ingredient	Yes can cost $20K for new ingredient	No	No	No	No	Yes - Free to air TV only
New Zealand	Cosmetic	No	Based on EU approved list	No	No	Industry self – regulatory code adopted – similar to ISO 22716:2007 Cosmetics GMP	Yes – recognise TGO 69, US, Canada and EU labelling as compliant.	No
ASEAN Region Including Brunei, Cambodia, Indonesia, Laos, Malaysia, Myanmar, Philippines, Singapore, Thailand and Vietnam	Cosmetic	No	Based on EU approved list	No	Yes	ISO 22716:2007 Cosmetics GMP	Pre-registration number required on packs in some ASEAN economies	No

Country	Regulatory Classification	Excipient approval	Active approval	Formulation approval	Pre-market registration	GMP	Packaging & Labelling	Pre-market advertising approval
European Union	Cosmetic	No	Yes	No	Yes Responsible person notifies each product. A Product Information Packet (PIP) is required for each product.	ISO 22716:2007 Cosmetics GMP	No	Pre-approval is required for all TV advertising of cosmetics
United States *Note: The U.S. Congress is currently considering a new Personal Care Product Safety Act that would mandate cosmetic GMPs and product registration.*	Over the counter (OTC)	No	Yes	No	Yes. Electronic drug product listing (notification) is required and is checked for all imports. Industry's voluntary Consumer Commitment Code expects each product to have a product safety file available for FDA inspection.	FDA current Good Manufacturing Practice in Manufacturing, Processing, Packing, or Holding of Drugs; 21 CFR Parts 210 and 211.	Yes – unique packaging with mandatory instructions, warnings and format (Drug Facts Box).	Not required. Claims restricted by Sunscreen Monograph.

Country	Regulatory Classification	Excipient approval	Active approval	Formulation approval	Pre-market registration	GMP	Packaging & Labelling	Pre-market advertising approval
Canada *Note: Health Canada is currently looking to reform sunscreen regulation and regulate these products as cosmetics*	Over the counter (OTC) drug (contains at least one "synthetic" active ingredient)	No	Yes	Yes	Yes - pre-market approval (45-180 days) and pre-market Drug Notification to Health Canada.	PIC/S GMP– cost estimates of importing an SPF products for first time Cdn$170k versus cosmetic Cdn$1k.	Yes - unique packaging and DIN approval numbers on pack.	Yes for print and TV advertising– claims restricted by monograph.
	Natural Health Product drug (contains only "natural" or mineral active ingredients)				Cdn$1,658 for in-monograph DIN; Cdn$3,000 for out-of-monograph DIN; no fee for NHP product license	Drug Establishment License (DEL) min. $14,000/annum - (Cdn$7,000 per activity and Cdn$7,000 per dosage form); No fee for NHP site license	Yes - unique packaging and NPN approval numbers on pack	

Case studies from Accord member companies

These examples demonstrate the excessive requirements imposed by the current regulatory framework for sunscreens which must be met in order for products to be made available for sale in Australia. Sunscreens are a low risk product category that should be managed with minimum effective regulation for supply to the Australian market.

CASE STUDY 1

The TGA inspected a manufacturing facility of a leading multinational Fast Moving Consumer Goods (FMCG) company, Company A, located in the US. This facility manufactures skin care products for sale in the US and internationally. This inspection formed part of Company A's application for TGA GMP certification for which a fee of $55k was payable to the TGA. Certification of this plant would have enabled Company A to import certain product ranges into Australia to provide skin moisturisers and anti-ageing products with SPF30 which Australian consumers are demanding for their daily skin care regimen. The site was fully compliant with the standards required by the US Food and Drug Administration (FDA). However, the TGA inspectors required additional conditions to be met before certification:

Stability Testing
The TGA required that at least one batch of any given product was tested each year. The current batch testing approach was one new product batch after each expiration period (one batch every 3 years) which was compliant with FDA requirements. The required systems changes to implement the new testing regime were complex and expensive and the TGA did not satisfactorily explain why this more onerous stability testing requirement was necessary.

Marketing Authorisation
Each product has its own market authorisation (registration or listing on Australian Register of Therapeutic Goods). When releasing a product for supply, the distributor must have market authorisation and must ensure production and release is in accordance with the current marketing authorisation. The TGA stated that the USA facility's product review did not include a review of Marketing Authorisation (to Australian) variations. This requirement is unreasonable, as Company A does not accept products that have a 'US SKU', therefore it would be impractical for the USA facility to review market authorization for each product.

Temperature and Ventilation
Temperature control and suitable ventilation were in place at the manufacturing facility in full compliance with stringent FDA standards. However, the TGA required the installation of additional specialised air filters which are both costly and unnecessary. Adequate temperature control systems were also in place but had been assessed as not meeting the onerous TGA requirements.

Outcome
Given that Australia is a relatively small export market, it did not make financial sense for Company A to invest in the expensive upgrades that were required to achieve TGA certification of their manufacturing facility. As a result, these products from Company A are not available for sale in Australia, with an estimated loss in sales revenue of $1.3M consolidated net sales per annum.

CASE STUDY 2

The TGA inspected the European manufacturing site of Company B, a leading multinational FMCG company specialising in skincare and hair care technology. The plant manufactures, fills and packs products for the consumer mass market and delivers its production worldwide. Only cosmetics products are manufactured on the site. The factory has two production units, one for skin care (face and body) and the other for hair care (masks and conditioners) and sun care products.

This inspection formed part of Company B's application for TGA GMP certification for which a fee of $44k was payable to the TGA. Certification of this plant would have enabled Company B to import a particular leading sunscreen range into Australia for launch onto the market in time for the summer 2014 season.

The manufacturing site conforms to ISO 22716 and is certified to ISO 9001. The TGA inspector refused to certify the facility unless two issues were addressed:

Compressed air

The facility uses compressed air to dry the production equipment after cleaning or sanitation to avoid microbiological (re)contamination and to move empty bottles along the production line to facilitate filling with product. The TGA inspection requested that the air be filtered using HEPA filters to a pharmaceutical standard which would cost around $20K each and would be expensive to maintain. Company B quality experts did not believe this degree of filtration was necessary for a plant which manufactures topically applied products for which microbial contamination was not an issue. Additionally, preservative efficacy testing of the formulas in question attest to the compliance of the formulas and their preservative systems. Given that the air quality in the facility had a proven track record and had been demonstrated to be at acceptable levels, this request was considered to be excessive for this type of product manufacture.

Temperature control

The TGA inspection raised a concern that the temperature in the temporary finished product storage areas was not controlled. The TGA required installation of temperature and humidity monitoring equipment throughout the facility. This is despite the fact that the facility had a temperate climate and that the temperature and humidity levels were consistent and within acceptable ranges. As a practical point to note, many Australians would be surprised that temperature monitoring would essentially prevent a sunscreen range from being launched in Australia when this a product that they take with them to the beach on very hot summer days.

Outcome

Given that Australia is a relatively small export market for Company B, it did not make financial sense to invest in these expensive installations that provided very little value-add to the overall quality system of the facility to achieve TGA GMP certification. As a result of the current regulatory environment, a leading global bets selling sunscreen product is still not available for sale to Australian families although it is available in New Zealand. The estimated loss in sales revenue to the business is $16M consolidated net sales per annum.

CASE STUDY 3

Company C, a leading multinational FMCG has been working since 2015 on introducing into the Australian market a sunscreen product which has been in supply for many years in the US, Canada and EU. The product may now not launch in Australia after the company has spent more than two years preparing for a launch scheduled for the summer of 2017/2018. This case study demonstrates how serious the Australian TGA PICs GMP licensing and ingredient regulation issues are impacting on this business.

Issues to be addressed for market entry into Australia included:

TGA acceptance of commonly used cosmetic ingredients
Company C had to have the supplier formulate a new blend that was ARTG/26BB compliant by substituting two ingredients from its global formulae for the Australian market. As a result, Company B now has to undertake in addition to the usual special Australian testing requirements other special testing to run on a formula currently being sold globally.

Currency of GMP license
This product line requires special and proprietary manufacturing and the 3rd party manufacturer is not yet GMP listed by the TGA. The GMP approval process commenced in January 2017 but the desktop audit had not commenced by May 2017. There is now a risk that the TGA may not provide the license because it is approaching the 2.5 year mark from the last US FDA inspection. Given that sunscreens are considered low risk products by the US FDA, the next GMP inspection is not expected to be for another two years. There is now a serious concern that if there is not an inspection at the three-year time point, the whole launch is at risk. Company C hopes to extend the current TGA license for a further year (3.5 years from the last inspection) and if US FDA does not re-inspect, then Company C will have to file for a TGA inspection at a cost of $40,000 or more. If the plant does not pass the TGA inspection, the launch will have completely failed and the damage to Company C's name and business with the trade will be significant.

From Company C's perspective*: I cannot value the time, effort and stress the GMP process places on me alone. At year 2, I start the worry of whether the US FDA will inspect in time for us to renew the license. This is not the way to run a business such as ours. At this time (May 2017), Marketing is going to meet and decide whether or not to abort the launch. They also do not want the risk of complete failure to supply the trade due to GMP license right after launching to the trade. Failure to launch will cost the business millions.*

CASE STUDY 4

Company D is an Australian -based company. The requirement for sunscreens to be listed medicines increases the time and cost to market of developing a sunscreen product in Australia. Several other jurisdictions recognise sunscreen products as safe for use and regulate these as cosmetic products such as the EU and ASEAN. These additional regulatory hurdles make it less viable for local cosmetic companies to formulate sunscreens and restricts the availability of products for Australian consumers.

There are also additional operational complexities associated with regulating sunscreens as listed medicines, for example these often require a separate Australian SKU that includes the unique AUST L number. There are also different labelling requirements such as listing the AAN for ingredients and specific warnings. This can be a deterrent for manufacturers that are required to create multiple SKUs. An export listing is also required if the same products is intended for sale overseas.

In order for an ingredient to be used in a listed medicine it must also be present on the ARTG. For example, polyacrylamidomethyl benzylidene camphor is a photostable UVA filter that has the ability to provide broad-spectrum protection, and is regulated under Cosmetics Europe's EC Regulation 1223/2009 as an acceptable UV filter at concentrations up to 6%. This particular filter, however, cannot be used in Australian sunscreen products as it is not listed on the ARTG. This significantly limits the ability of Australian manufacturers to formulate innovative sunscreen products, as well as restricting the import of other sunscreen products that have been established as safe overseas. This is particularly concerning given Australia has one of the highest rates of skin cancer in the world and consumers should be able to access new and innovative sun protection products.

As an Australian-based company, it formulates to Australian standards so while products are complaint with TGA regulations, innovation protects are greatly stifled by the somewhat limited array of ingredients available on the ARTG. This does not include infrared active ingredients, which are becoming increasingly necessary to protect not only against UV damage, but IRA exposure, which is accountable for approximately one-third of solar energy and therefore exposure.

From Company D's perspective: *We manufacture all products in TGA approved facilities which simplifies the manufacturing process for sunscreens. However, several small-to-medium enterprises would be limited by the fact that sunscreens must be developed in such a facility. The risks associated with properly formulated and tested sunscreens are relatively low, and compliance with GMP standards could be easily be achieved, as is the case with other cosmetic products in Australia*.